interviews (16) were then conducted using a specific interview guide. Transcripts were analysed using thematic analysis to extract concepts related to satisfaction with treatments and to organise them into a model. Items were generated for each concept of interest using patients' words. The resulting test version of the questionnaire was tested for relevance and comprehension with 7 patients and revised accordingly; the new version was tested on a second set of 5 patients and revised to provide the pilot version. A clinician advisory board was involved at each milestone of the questionnaire development for validation. **RESULTS:** The test questionnaire assessed treatment satisfaction through 49 questions and 67 items, organised into 5 sections: treatment efficacy, side-effects, convenience and constraints, global impact, and satisfaction. Conceptual content of the questionnaire includes comparison to prior state and to expectations, satisfaction, acceptability, and intentions. The questionnaire was globally well-accepted by patients during the tests; few modifications were made in the structure and some items were reformulated. The pilot version (62 items) was finalised after the second round of comprehension tests. **CONCLUSIONS:** The questionnaire is a unique tool to assess treatment satisfaction in patients with severe Crohn's disease treated by anti-TNF. A scoring and validation study is currently being completed before the questionnaire can be included in clinical research and epidemiological studies.

PSY46

HEALTH-RELATED QUALITY OF LIFE BURDEN AMONG FIBROMYALGIA PATIENTS: RESULTS FROM A CROSS-SECTIONAL STUDY IN FRANCE

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OBJECTIVES: Fibromyalgia (FM), a chronic disorder characterized by persistent, widespread pain, has a **major impact on health-related quality of life (HRQoL).** However, little is known about the impact of FM severity on HRQoL in a European population. **This cross-sectional, observational study evaluated the impact of FM** severity on HRQoL among French subjects. **METHODS:** A cross-sectional study recruited 88 FM subjects during routine visits to community-based physicians in France. **Subjects described their pain and HRQoL using the Brief Pain Inventory (BPI),** Fibromyalgia Impact Questionnaire (FIQ), EuroQol- 5 questionnaire (EQ-5D), Hospital Anxiety and Depression Scale (HADS), and the Medical Outcomes Study (MOS) Sleep Scale. FM severity was defined using subjects' FIQ total scores: 0–<39 (mild), 39–<59 (moderate), and 59–100 (severe). Site staff completed case report forms using subjects' medical records. Impact of FM severity on HRQoL was investigated using analysis of variance models. **RESULTS:** The mean age (SD) of subjects was 55.2 (11.8) years, and 84% were female. The mean (SD) FIQ total score was 54.8 (17.3), with most patients reporting moderate (38%) or severe (43%) FM. Subjects demonstrated poor HRQoL scores, which worsened as **FM severity worsened. The mean values (SD)** by FM severity (mild, moderate, severe) were 0.65 (0.18), 0.44 (0.27) and 0.18 (0.33) for the EQ-5D; 8.00 (4.08), 9.94 (2.89), and 11.92 (4.42) for HADS anxiety; and 4.71 (3.04), 6.58 (3.33), and 10.53 (4.02) for HADS depression ($p < 0.0001$ for all comparisons). A significant association with FM severity was found for the MOS Sleep Problems Index ($p = 0.003$), BPI Pain Intensity ($p < 0.0001$), BPI Pain Severity Index ($p < 0.0001$), and BPI Pain Interference Index ($p < 0.0001$). **CONCLUSIONS:** FM had a substantial negative impact on HRQoL, which increased as FM severity worsened. These data allow for more precise understanding and quantification of mild, moderate, and severe FM health states.

PSY47

VALIDATION OF THE FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY (FACIT)—FATIGUE SCALE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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OBJECTIVES: Fatigue is a common symptom of systemic lupus erythematosus (SLE). Our objective was to validate the 13-item FACIT-Fatigue scale in SLE patients. **METHODS:** The FACIT-Fatigue scale, Brief Pain Inventory (BPI) and Patient Global Assessment Visual Analog Scale (PGA) were completed at baseline and weeks 12, 24, and 52 by patients with moderately-severely active extra-renal SLE, participating in a rituximab clinical trial (EXPLORER). The SLE Disease Activity Index (SLEDAI) and the British Isles Lupus Assessment Group (BILAG) disease activity index were completed by physicians at the same visits. **RESULTS:** At baseline, 254 patients completed the FACIT-Fatigue. The mean (19.1) was substantially lower than the US average (40.1). Cronbach's alpha was >0.95 at all visits. In cross-sectional analyses, FACIT-Fatigue differentiated between groups defined by BILAG General domain ratings; effect sizes (mean difference/SD) were generally in the 0.5–0.6 range. FACIT-Fatigue had moderate-high correlations ($r = 0.6–0.7$) with BPI and PGA, but poor correlations with BILAG and SLEDAI total scores ($r = 0.24–0.29$). At weeks 12, 24 and 52, patients with improved or unchanged BILAG General status compared to baseline experienced a statistically significant improvement in FACIT-Fatigue with effect sizes in the range of 0.3–0.7. Mean FACIT-Fatigue improvement was higher in patients who improved vs. remained unchanged on the BILAG General domain. FACIT-Fatigue scores remained stable for patients with worsened BILAG General domain ratings compared to baseline (effect sizes generally <0.3). Distribution and anchor-based estimates suggested a minimally important difference (MID) range of 3–6 points. **CONCLUSIONS:** The FACIT-Fatigue is a valid and responsive measure of fatigue in patients with SLE. MID in SLE sample is similar to that derived previously in other populations. Since few patients experienced worsening of BILAG General status in this study, further research is warranted to evaluate the responsiveness of FACIT-Fatigue to worsening in this population.

PSY48

INSOMNIA AMONGST PATIENTS WITH CHRONIC PAIN AND INFLUENCE OF ADJUSTMENT OF PAIN MEDICATION IN GERMANY

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OBJECTIVES: Patients with chronic pain often suffer from insomnia. It is defined as a difficulty in initiating or maintaining sleep, which decreases quantity and quality of sleep. The combination of chronic pain and insomnia has thus a huge impact of quality of life. The aim was to assess the extent of insomnia amongst patients with chronic pain and how far an adjustment of medical therapy could improve the well-being of these patients. **METHODS:** In 2008, the Deutsche Gruene Kreuz e. V. in collaboration with Johannes Horlemann developed a questionnaire which was distributed in several medical sites across Germany. In order to assess the impact of treatment to insomnia 113 patients with chronic pain were requested to complete the paper questionnaire before and after the stable adjustment of pain medication. **RESULTS: Most patients** suffered from pain for several months and received pain medication. Before the initiation of new treatment half of the respondents reported that falling asleep took more than one hour and that the total sleep duration was less than 5 hours. In addition, 90% reported a disturbance of sleep by pain several times per night. As a result, only 13% of patients felt relaxed and awake in the next morning. However, the difficulties in falling asleep and maintaining sleep were definitely diminished after the adjustment of pain medication. Beside the reduction of use of sleeping pills three quarter of all respondents reported to feel better after sleeping. **CONCLUSIONS: The majority of** chronic pain patients suffer from insomnia. It causes serious difficulties in initiating or maintaining sleep. The adjustment of pain medication considerably influenced almost all aspects of insomnia. Therefore, it is reasonable to consider a change in treatment of chronic pain patients to improve the quality and quantity of sleep and thus achieve an increase in quality of life.

PSY49

VALIDATION OF THE SF-36 IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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OBJECTIVES: Systemic lupus erythematosus (SLE) has a significant impact on patients' health-related quality of life (HRQOL). The purpose of this study was to validate the SF-36 for use in moderately-severely active extra-renal SLE patients. **METHODS:** 254 SLE patients, participating in a rituximab clinical trial (EXPLORER), completed the following scales at baseline, weeks 12, 24, and 52: the SF-36, Brief Pain Inventory (BPI), and Patient Global Assessment Visual Analog Scale (PGA). Physicians completed the SLE Disease Activity Index (SLEDAI), and the British Isles Lupus Assessment Group (BILAG) disease activity index at the same visits. **RESULTS:** All SF-36 scores were 1–2 standard deviations lower than the US general population at baseline. Cronbach's alpha was >0.80 at all visits. In cross-sectional analyses, the SF-36 Physical Component Summary (PCS) scores differentiated between groups defined by BILAG General and Musculoskeletal domain ratings at most visits. SF-36 scores had moderate-high correlations with BPI and PGA ($r = 0.40–0.65$). Mean changes from baseline in the eight SF-36 domain scores, as well as the PCS and Mental Component Summary (MCS), were generally in agreement with improved, unchanged and worsened PGA scores. Patients with improved or unchanged BILAG General and Musculoskeletal status compared to baseline experienced a statistically significant improvement in most SF-36 PCS scores with effect sizes (mean change / SD) 0.3–0.7. Scores remained stable for patients with worsened BILAG ratings (effect sizes generally <0.3). Based on distribution and anchor-based methods the minimally important differences (MID) was estimated to be approximately 3–6 points. **CONCLUSIONS:** The SF-36 is a valid and responsive measure of HRQOL in patients with SLE. MIDs in the SLE sample are similar to those derived previously in other populations. Since few patients experienced worsening of BILAG General and Musculoskeletal domains, further research is warranted to evaluate responsiveness of the SF-36 to worsening in this population.

PSY50

THE EFFECT OF OBESITY ON PHYSICAL AND MENTAL HEALTH

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OBJECTIVES: According to WHO, obesity is a contemporary disease which threatens peoples' health and health-related quality of life (HRQoL). The prevalence of obesity in Greece, in both genders, is among the highest in Europe. Despite the cost of treating obesity, research in this area is generally under-funded. The aim of the study was to assess the physical and mental health of Greek obese people compared to the general (non-obese) population. **METHODS:** Data was obtained from a representative sample ($N = 981$) of the general non-institutional population in Greece. The study was carried out in 2006 and participants were face-to-face interviewed. Participants with a BMI ≥ 30 kgr/m^2 ($N = 161$) were compared to the rest of the sample in terms of physical and mental health as measured by the SF-12 questionnaire The confounding effect of demographic (gender, age, education) and disease-related variables (hypertension, hyperlipidaemia, diabetes and other cardiovascular problems) were controlled for using ANCOVA. **RESULTS:** Most obese participants were female (57.8%) and the